

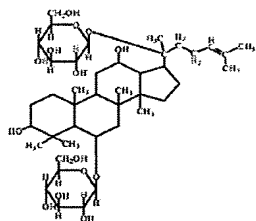
REMARKS

Claim 1 has been replaced by claim 18 which has been written in product-by-process form. Support for this claim is found at page 3 lines 14 - 3 from the bottom of the page.

The only issue raised in the final rejection is whether the invention as claimed in claims 18 and 2-12, is prima facie obvious over a combination of Gai et al Chinese Publication CN 1,273,114 and Su US Patent 4,968,675.

Gai teaches production of an injectable composition from a saponin-containing powder obtained from notoginseng by “mixing it with injection water, regulating pH value, boiling the solution adding activated carbon, filtering and fine-filtering”. Su teaches production of an injectable amino-steroid drug by dissolving the active compound in a citric acid solution and then stirring in sodium citrate and sodium chloride. The product is then filtered.

The examiner argues that the active compound of Su is similar to the saponins of Gai so that the teaching of Su may be applied to “fill in the blanks” of Gai’s disclosure. As pointed out previously, the applicants do not agree the active compounds of Gai and Su are different in key respects. Su is concerned with salts of 16.alpha.-methyl-21-[4-[2,6-bis(1-pyrrolidinyl)-4-pyrimidinyl]-1-piperazinyl]pregna-1,4,9(11)-triene-3,20-dione. In order to achieve this, Su turned to teachings relating to Ellipticine (5,11-Dimethyl-6*H*-pyrido[4,3-*b*]carbazole). These are both nitrogen-containing compounds. There is, however, no reason to think that teaching relating to either of these compounds is relevant to saponins obtained from notoginseng. Saponin RG1 referred to in the examples of the present application does not contain nitrogen. It has the formula:



There is therefore no real basis for combining the teachings of Gai and Su.

Even if there were, however, this would not result in the invention as now claimed. As noted above, Gai includes a mandatory boiling step. The compositions of the present invention are not heated during their preparation. This in itself results in a difference in the nature of the product obtained.

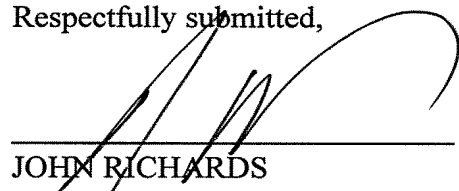
It is well known that saponins as active pharmaceutical ingredients are highly sensitive to temperature and pH. Thus, the steps of heating and adjusting the pH during production will substantively affect the content and the stability of active ingredient(s) and hence the nature of the final products. In the manufacture of the product of the present invention, the solution is not heated after dissolving the saponin family of Radix Notoginseng into solvent and then adjusting the pH of the solution, thereby avoiding effectively a potential degradation of active ingredients and an uncertain change of pH. Example 9 of the present invention demonstrates the advantage of the product of the present invention over the product taught by Gai et al, i.e., a higher stability of pH.

It can be seen from the above that the amended claims are not obvious over the cited references, and meets the requirements of 35 USC 103.

It is therefore submitted that this application is in order for allowance and an early action to this

end is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John Richards', is written over a horizontal line.

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